

## § 405.2122

## 42 CFR Ch. IV (10–1–05 Edition)

availability of care, the quality of care, and the efficient utilization of equipment and personnel, based on the following evidence:

(a) Information on the geographic distribution of ESRD patients and facilities;

(b) Information on quality of care; and

(c) Information on operational and management efficiency.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 55 FR 23440, June 8, 1990]

### § 405.2122 Types and duration of classification according to utilization rates.

A renal transplantation center that meets all the other conditions for coverage of ESRD services will be classified according to its utilization rate(s) as follows: Unconditional status, conditional status, exception status, or not eligible for reimbursement for that ESRD service. Such classification will be based on previously reported utilization data (see § 405.2124, except as specified in paragraph (a) of this section), and will be effective until notification of subsequent classification occurs. (See § 405.2123 for reporting requirements; § 405.2124 for method of calculating rates: § 405.2130 for specific standards.)

(a) *Initial classification.* (1) A renal transplantation center that has not previously participated in the ESRD program will be granted conditional status if it submits a written plan, detailing how it will achieve the utilization rates for conditional status by the end of the second calendar year of its operation under the ESRD program, and the rates required for unconditional status by the end of its fourth calendar year of operation.

(2) The renal transplantation center's performance will be evaluated at the end of the first calendar year to ascertain whether it is properly implementing the plan.

(b) *Exception status.* (1) A renal transplantation center that does not meet the minimum utilization rate for unconditional or conditional status may be approved by the Secretary for a time limited exception status if:

(i) It meets all other conditions for coverage under this subpart;

(ii) It is unable to meet the minimum utilization rate because it lacks a sufficient number of patients and is located in an area without a sufficient population base to support a center or facility which would meet the rate; and

(iii) Its absence would adversely affect the achievement of ESRD program objectives.

(2) A hospital that furnishes renal transplantation services primarily to pediatric patients and is approved as a renal dialysis center under this subpart, but does not meet the utilization standards prescribed in § 405.2130(a), may be approved by the Secretary for a time limited exception status if:

(i) It meets all other conditions for coverage as a renal transplantation center;

(ii) The surgery is performed under the direct supervision of a qualified transplantation surgeon (§ 405.2102) who is also performing renal transplantation surgery at an approved renal transplantation center that is primarily oriented to adult nephrology;

(iii) It has an agreement, with the other hospital serviced by the surgeon, for sharing limited resources that are needed for kidney transplantation; and

(iv) There are pediatric patients who need the surgery and who cannot obtain it from any other hospital located within a reasonable distance.

[43 FR 48951, Oct. 19, 1978, as amended at 45 FR 58124, Sept. 2, 1980; 51 FR 30362, Aug. 26, 1986; 55 FR 23440, June 8, 1990]

### § 405.2123 Reporting of utilization rates for classification.

Each hospital furnishing renal transplantation services must submit an annual report to CMS on its utilization rates. The report must include both the number of transplants performed during the most recent year of operation and the number performed during each of the preceding 2 calendar years.

[55 FR 23441, June 8, 1990]